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A retrospective analysis of 500 ERCP procedures: outcomes, adverse events, and risk factors over two years

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ABSTRACT

Aims: Endoscopic retrograde cholangiopancreatography (ERCP) is a widely used procedure for both the diagnosis and management of biliary and pancreatic ductal diseases. While it has been largely replaced by non-invasive imaging techniques for diagnostic purposes, ERCP remains the gold standard for therapeutic interventions. This study aims to retrospectively analyze the outcomes, adverse events, and success rates of ERCP procedures performed on 500 patients over two years.

Methods: A retrospective review of 500 ERCP procedures performed at a single center over 24 months was conducted. Patient demographics, indications for ERCP, procedural outcomes, and adverse event rates were collected and analyzed. Success rates for therapeutic interventions, as well as risk factors for post-procedural adverse events, were identified.

Results: The study revealed that 448 (89.6%) of ERCP procedures were successful in achieving the primary therapeutic goal (e.g., stone extraction, stent placement). Adverse events occurred in 93 (18.6%) of cases, with post-ERCP pancreatitis being the most common adverse event (n: 73, 14.6%). Risk factors associated with adverse events included previous cholecystectomy ($p<0.001$), difficult cannulation ($p<0.001$), and prolonged procedure time (p:0.003).

Conclusion: ERCP remains a highly effective treatment tool for treating biliary and pancreatic diseases, although it carries the risk of many adverse events. The identification of key risk factors may help to minimize the incidence of adverse events and improve patient outcomes. The data collected in this study provide valuable insight into the current practice of ERCP and the role it plays in modern gastroenterology.

Keywords: ERCP, biliary diseases, therapeutic endoscopy, post-ERCP pancreatitis, adverse event rates, retrospective study

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive endoscopic procedure that is used in the diagnosis and treatment of diseases affecting the bile ducts and the pancreatic duct. First developed in 1968, ERCP has an important role in diagnosing conditions such as bile duct stones, strictures, malignancies, pancreatitis, and bile duct obstructions.[1] Today, the use of ERCP is on the rise, particularly in elderly populations with high comorbidity and in regions where the prevalence of biliary diseases is rising.[2]

In recent years, the diagnostic use of ERCP has become more limited, as less invasive techniques like magnetic resonance cholangiopancreatography (MRCP) have gained favor.[3] However, ERCP remains the gold standard for therapeutic interventions including stone extraction, stenting, dilating biliary strictures, and palliating malignant lesions.[4]

In this retrospective study, 500 patients who underwent ERCP over two years were analyzed. The study focused on demographic data, diagnostic distribution, adverse event rates, and treatment outcomes. This study aims to update data on the efficacy and safety of ERCP and the identification of risk factors for adverse events during the procedure.

METHODS

Ethics

This study was conducted in accordance with the Declaration of Helsinki and approved by the Scientific Research Ethics Committee of Health Sciences University Ankara Training and Research Hospital (Date: 08.05.2024, Decision No: 107/2024). Informed consent was not required due to the retrospective nature of the study.

Study Design and Population

This retrospective study was conducted at Ankara Training and Research Hospital, reviewing all ERCP procedures performed over two years from January 2022 to December 2023. A total of 500 patients undergoing ERCP for various indications, such as biliary stones, strictures, malignancy, cholangitis, and other biliary or pancreatic diseases were included. Patients with incomplete medical records or who underwent ERCP for diagnostic purposes only were excluded (23 patients).

Data Collection

Data were collected from patient medical records and procedure reports. The following variables were documented:

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patient demographics (age, gender), comorbidities (diabetes, hypertension, etc.), indication for ERCP (e.g., biliary stones, malignancy, cholangitis), type of therapeutic intervention (sphincterotomy, stone extraction, stent placement), procedural success rate, and immediate or delayed adverse events (e.g., post-ERCP pancreatitis, bleeding, perforation, infection).

ERCP Procedure

All procedures were performed by experienced gastroenterologists using standard endoscopic equipment. Conscious sedation or general anesthesia was administered by an experienced anesthesiologist depending on the clinical condition of the patient. Cannulation of the common bile duct or pancreatic duct was achieved using standard catheterization techniques. Therapeutic interventions, such as biliary or pancreatic sphincterotomy, stone extraction, balloon dilatation and stent placement were performed as indicated. Fluoroscopy was used to guide the procedures and to confirm successful interventions. In all procedures, 100 mg rectal indomethacin was administered before the procedure for pancreatitis prophylaxis.

Cholangitis Diagnosis and Severity

Cholangitis was diagnosed based on the Tokyo Guidelines requiring evidence of systemic inflammation (fever, elevated white blood cell count) along with biliary obstruction.[5] The severity of cholangitis was categorized as mild, moderate, or severe based on clinical presentation, including organ dysfunction and response to treatment.

Post-ERCP Pancreatitis

Post-ERCP pancreatitis was defined using the Cotton criteria.[6] This includes the presence of new or worsening abdominal pain occurring within 24 hours after ERCP, accompanied by a serum amylase or lipase level at least three times greater than the upper limit of normal. Imaging findings are not required for the diagnosis, except in severe cases where clinical signs are consistent with pancreatic inflammation.

Outcomes

The primary outcomes were the success rate of therapeutic interventions, defined as the successful completion of the intended therapeutic procedure, and the occurrence of procedure-related adverse events. Secondary outcomes included long-term clinical success, defined as the resolution of symptoms and absence of disease recurrence over a 6-month follow-up period.

Assessment of Adverse Events

Adverse events were categorized as immediate (e.g., bleeding, perforation) or delayed (e.g., post-ERCP pancreatitis, infections). Post-ERCP pancreatitis was diagnosed based on the criteria outlined above. The severity of adverse events, including cholangitis and pancreatitis, was classified according to established clinical guidelines (e.g., Tokyo Guidelines for cholangitis and Cotton criteria for pancreatitis).

Statistical Analysis

Data were recorded into a database for statistical analysis. Descriptive statistics summarized patient characteristics and procedural outcomes. Continuous variables were expressed as means with standard deviations, while categorical variables were expressed as frequencies and percentages. Chi-square tests were used to compare categorical variables, and independent t-tests were used to analyze continuous variables. A p-value of <0.05 was considered statistically significant.

RESULTS

The study was designed to include 523 patients, 23 were excluded due to missing data, and 500 were included. A total of 500 ERCP procedures of these 500 patients were evaluated in the study. 101 patients underwent ERCP for the 2nd time, 21 for the 3rd time, 5 for the 4th time and 1 each for the 5th, 6th and 7th time.

Of these patients included in the study, 271 (54.2%) were female, and the mean age of patients was 62.1 years. In these 500 ERCP procedures, most patients (n: 351,70.2%) presented to the hospital with abdominal pain. The most common comorbidity was hypertension (n: 225, 45%), followed by coronary artery disease (n: 133,26.6%), and diabetes mellitus (n: 123, 24.6%). The baseline characteristics of the patients are shown in Table 1.

Table 1. The baseline characteristics of patients

Patients	n (%)	SD
Age	62.1	±18.5
Female gender	271 (54.2)	
History of cholecystectomy	147 (29.4)	
History of previous ERCP	174 (34.8)	
Comorbid diseases		
Cardiac disease	133 (26.6)	
Hypertension	225 (45)	
Diabetes mellitus	123 (24.6)	
Chronic kidney disease	16 (3.2)	
COPD / astma	43 (8.6)	
Neurological disease	26 (5.2)	
Presentation		
Abdominal pain	351 (70.2)	
Jaundice	178 (35,6)	
Fever	80 (16)	
Dark urine color	61 (12.2)	
Weight loss	19 (3.8)	
Pruritis	19 (3.8)	
Antiaggregant medication use	136 (27.2)	
Anticoagulant medication use	32 (6.4)	

SD: Standard deviation, ERCP: Endoscopic retrograde cholangiopancreatography, COPD: Chronic obstructive pulmonary disease

Of the total ERCP procedures, 147 patients had a history of cholecystectomy prior to ERCP, while 174 patients had a history of previous ERCP. Six patients had a history of gastric surgery. ERCP procedure time ranged from 10 to 65 minutes (mean 31.19 minutes±10). While 166 (33.2%) of the patients had a sphincterotomized papilla prior to the procedure, cannulation was successful in 458 (91.6%) of the total procedures. The most common technique used in cannulated patients was the use of guidewire (n: 375, 75%), followed by precut (n: 40, 8%) and double guidewire (n: 29 and 5.8%). While only 10 (2.2%) of 458 cannulated patients had a normal ERCP result, 448 (97.8%) patients had a pathological result. The most common indication for ERCP was choledocholithiasis with 86.8% (n: 434), followed by malignant biliary stricture (n: 36, 7.2%) and bile leakage due to bile duct injury (n: 12, 3.2%).

The indication for ERCP was determined by USG in 61.2% of the patients, by CT in 18.2%, and by MRCP in 20.6%. ERCP revealed no stones in 13.2% (n:66) of patients, a single

stone in 39.1% (n:193), and multiple stones in 48.2% (n:241). While stones in 17 patients (3.9%) could not be removed by ERCP e, stones in 387 patients (89.1%) were removed using a stone extraction balloon. In patients with malignancy, the most common cancer was pancreatic cancer with 25 patients, followed by cholangiocellular cancer (n: 4) and ampullary cancer (n: 3).

Prior to the procedure, 33.2% (n: 166) of our patients undergoing ERCP had no cholangitis, 43.4% (217) had mild cholangitis, 19.2% (n: 96) had moderate cholangitis, and 4.2% (n: 21) had severe cholangitis. A post-procedural adverse event occurred in 93 (18.6%) of 500 ERCP procedures. Post-ERCP pancreatitis developed in 73 (14.6%) of these patients. Other adverse events included bleeding in 10 patients, ascending cholangitis in 7 patients, and cardiovascular adverse events in 3 patients. Adverse event rates in patients are shown in Figure 1.

Endoscopic sphincterotomy was performed in 276 (55.2%) of the ERCP procedures, balloon dilatation was performed in 181 (36.2%), and a stent was placed in the common bile duct in 274 (54.8%) procedures. Patients who experienced adverse events during ERCP took longer to treat than those who did not (p:0.003).The use of anticoagulant and antiaggregant therapy was not associated with the risk of adverse events after ERCP. Total procedure time was significantly longer in patients who experienced adverse events after ERCP (p:0.003). In addition, previous sphincterotomy significantly reduced the risk of adverse events (p<0.001). Among patients who could be cannulated, those who were difficult to cannulate had a significantly higher rate of adverse events than those who were easy to cannulate (p<0.001). Table 2 compares patients about adverse events.

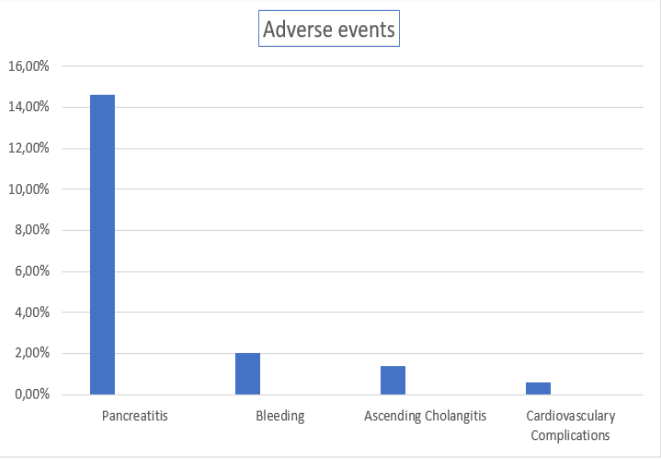

Figure 1. Adverse event rates in patients

When the laboratory results of the patients were evaluated; mean total bilirubin was 3.2 mg/dl (+ 3.17), direct bilirubin was 2.5 mg/dl (+2.7), gamma glutamyl transtransferase was 366 IU/ml (+367), alanine aminotransferase was 145 IU/ml (+159), aspartate aminotransferase was 124 IU/ml (+147), and white blood cell count was 9300 IU/ml (+4500).A statistically significant higher rate of post-ERCP pancreatitis was observed in patients who underwent endoscopic sphincterotomy during ERCP (22.8%) compared to thosewho did not (4.5%), (p<0.001).

When the patients who underwent the procedure were divided into two groups as elderly (>65 years old) and young, 268 (53.6%) patients were young and 232 (46.4%) patients were elderly . The rate of successful cannulation in elderly patients was statistically significantly lower than in younger patients, 87.1% and 95.5%, respectively, (p:0.001).

Additionally, when the risk of developing post-ERCP pancreatitis was evaluated in elderly and young patients, iit was found to be higher in younger patients (17.2%) than in older patients (11.6%), but this value did not reach a statistically significant level, p: 0.081. ERCP procedure time was longer in patients who developed post-ERCP pancreatitis (34.9 min) than in patients who did not develop pancreatitis (30.5 min), (p:0.007). Procedure-related variables and adverse events in older and younger patients are shown in Table 3.

DISCUSSION

This study evaluated 500 ERCP procedures over two years, providing significant insights into patient demographics, indications, adverse events, and associated risk factors. The mean age of the patients was 62.1 years, with a notable predominance of females (54.2%). This finding aligns with previous literature suggesting that ERCP procedures are frequently performed in older populations with complex medical histories. The most common presenting symptom was abdominal pain (70.2%), which is in line with existing studies suggesting that biliary obstruction is often associated with pain.[7]

Table 2. Comparison of variables associated with patients and procedure in terms of adverse events

Variables	Adverse events (n, range, %)	Non-adverse events (n, range, %)	p
Age	59.7 (20-94)	62.7 (20-97)	0.17
Gender Female Male	 46 (17) 47 (20.5)	 225 (83) 182 (79.5)	0.31
History of cholecystectomy Non- cholecystectomy	13 (8.8) 80 (22.7)	134 (91.2) 273 (77.3)	**<0.001**
Antiaggregant medication use Antiaggregant medication non-use	27 (19.9) 66 (18.1)	109 (80.1) 298 (81.9)	0.66
Anticoagulant medication use Anticoagulant medication non-use	9 (28.1) 84 (17.9)	23 (71.9) 384 (82.1)	0.15
Total procedure time (min)	34.3	30.4	**0.003**
History of sphincterotomy Non-sphincterotomy	12 (7.2) 81 (24.2)	154 (92.8) 253 (75.8)	**<0.001**
Difficult cannulation Easy cannulation	50 (64.9) 43 (11.2)	27 (35.1) 338 (88.8)	**<0.001**

Table 3. Comparison of variables in terms of age

Variables	Young patients (%)	Elderly patients (%)	p
Patients	268 (53.6)	232 (46.4)	0.44
Successful cannulation	256 (95.5)	202 (87.1)	0.001
Adverse events	57 (21.3)	36 (15.5)	0.1
Post-ERCP pancreatitis	27 (11.6)	46 (17.2)	0.081
Total procedure time (minute)	31.8	30.4	0.13

ERCP: Endoscopic retrograde cholangiopancreatography

The predominance of choledocholithiasis as an indication for ERCP (86.8%) is in line with established findings and reaffirms the necessity for timely intervention in patients presenting with biliary stones.[8] It has been emphasized in the literature that the early diagnosis and treatment of choledocholithiasis can significantly reduce the morbidity and mortality rates associated with adverse events resulting from untreated conditions.[9] In this study, the overall adverse event rate of 18.6% is in line with previous studies and confirms that although ERCP is an important intervention, it is not without risk.[10]

The observed incidence of post-ERCP pancreatitis (PEP) in our study was 14.6%, which is considered a relatively high rate compared to typical reports in the literature. While this rate aligns with some published data, it exceeds the threshold suggested by ESGE guidelines. Several factors may contribute to the elevated incidence observed in our cohort. One potential explanation is the higher proportion of patients undergoing balloon dilation procedures, which are known to be associated with increased risk of PEP. Additionally, the extended duration of ERCP procedures in some cases could have contributed to a higher likelihood of pancreatitis. These procedural factors, combined with patient-specific risk factors, might explain the increased PEP rate in our study. It is important to consider these variables when evaluating our results in the context of the broader literature.[11]

In particular, we identified several risk factors associated with adverse events. Previous studies have indicated that patients with a history of sphincterotomy experience fewer adverse events.[3] In our cohort, prior sphincterotomy significantly reduced the risk of post-procedural adverse events, which may reflect the benefits of prior interventions in optimizing biliary drainage and preventing subsequent adverse events. Moreover, the duration of the procedure was significantly longer in patients who developed adverse events, suggesting that prolonged procedures may increase the risk of adverse outcomes, further emphasizing the importance of efficient technique and procedural timing in ERCP management.[12]

In contrast, the use of anticoagulants and antiaggregant medications did not appear to correlate with increased adverse event rates in our study, challenging some existing assumptions about their safety in ERCP procedures.[13] This many practitioners remain wary of performing procedures in patients receiving these medications due to potential bleeding risks, this finding is particularly relevant to clinical practice. However, our results may suggest that using such drugs could be safely incorporated into ERCP protocols if managed appropriately.[14] Furthermore, consistent with the understanding that operator skill and technique play a critical role in minimizing adverse outcomes,[8,10] our analysis showed that difficult cannulation was associated with a higher rate of adverse events.[8,10]

Analysis by age showed that younger patients had a higher rate of post-ERCP pancreatitis than their older counterparts, although this finding did not reach statistical significance. This observation is consistent with the hypothesis that younger patients may have a stronger physiological response to procedural stressors.[15] Indeed, younger individuals may have different anatomical and physiological characteristics that may predispose them to increased risks during the procedure.[16] This finding warrants further investigation to better understand the underlying mechanisms at play.

CONCLUSION

As a result, this study highlights the complexities and risks associated with ERCP procedures. A thorough understanding of the demographics of the patients, the presenting symptoms, and the nuances of the procedure can help healthcare professionals refine their approach to ERCP and ultimately improve patient safety and outcomes. As ERCP continues to evolve with advancements in technology and techniques, ongoing education and training for endoscopists is paramount to minimizing risks and optimizing patient care. Future studies should continue to explore the interplay of these factors, with a focus on large, multicenter trials to improve our understanding of ERCP-related adverse events and develop evidence-based guidelines for practice.[17]

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was conducted with the permission of the Health Sciences University Ankara Training and Research Hospital Clinical Researches Ethics Committee (Date: 08.05.2024, Decision No: 107/2024).

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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